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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,966	12/05/2001	Wesley H. Verkaart	70869-0083	1396

7590

01/13/2003

Clark & Brody  
Suite 600  
1750 K Street, NW  
Washington, DC 20006

EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 01/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/001,966

Applicant(s)

Verkaart et al.

Examiner

Sandra Saucier

Art Unit

1651

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1, 5, 4 6) ☐ Other: \_\_\_\_\_

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#### DETAILED ACTION

Claims 1-20 are pending and are considered on the merits.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-10, 12-16, 18-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5789147 [IDS].

The claims are directed to a composition comprising blood, anticoagulant and a washing solution, whereby the anticoagulant is inert (CPD or heparin) and the washing solution comprises starch and a method of making the composition.

The references are relied upon as explained below.

US 5,789,147 discloses a composition comprising blood, CPD and a rouleaux reagent comprising Heptastarch (col. 5, l. 66, and col. 6, l. 44). The blood/anticoagulant mixture is mixed with the starch and the red cells sedimented (col. 6, l. 1-9). Although the concentration of red cells in the sedimented layer is not given in terms of hematocrit, less than 10% of red cells are in the supernatant layer in the method of '147 (col. 5, l. 12). This is considered to fall within the claim limitations in the absence of evidence to the contrary.

Claims 1-3, 5-9, 12-16, 18, 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,879,318 [IDS].

US 5,879,318 discloses a composition comprising blood, CPD and a rouleaux reagent comprising Hetastarch (col. 5, l. 48, and col. 6, l. 20-29 and claim 3). The blood/anticoagulant 7:1 mixture (col. 5, l. 47) is mixed with the starch and the red cells sedimented (col. 6, l. 1-9) and the supernatant containing the white cells is removed (col. 5, l. 31-38).

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Claims 1, 4-6, 11-13, 15, 17-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by CN 85103712 [N].

CN 85103712 discloses a composition for separating blood cells comprising CM-starch, heparin, glucose, NaCl. The mixture is added to blood and effects the sedimentation of red cells.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-9, 12-16, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,879,318 [IDS]

The claims have been discussed above.

The references are relied upon as explained below.

US 5,879,318 teaches the use of heparin among other anticoagulants and exemplifies CPD as the anticoagulant of choice in a composition comprising blood, anticoagulant and HES (col. 4, l. 44). The composition is used to sediment the red cells from the blood.

It would have been obvious to use heparin as an anticoagulant in a ratio of 1/7 in a process of adding HES, preferably between 1-6% (col. 4, l.40) and forming a mixture of blood, heparin 7/1 and 6% HES in order to sediment red cells because '318 generically teaches this method and composition in the

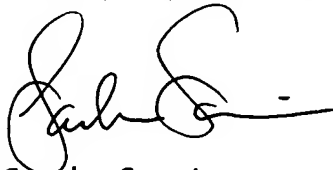
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absence of unexpected results.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the reference with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier  
Primary Examiner  
Art Unit 1651  
January 7, 2003